(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 281 355 B1

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
21.09.2005 Bulletin 2005/38

(51) Int Cl.[7]: **A61B 17/00**

(21) Application number: **02016922.3**

(22) Date of filing: **31.07.2002**

(54) Tissue opening occluder

Okklusionsvorrichtung

Dispositif d'occlusion

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR IE IT LI LU MC NL PT SE SK TR

(30) Priority: **01.08.2001 US 309376 P**
01.08.2001 US 309418 P
01.08.2001 US 309337 P
30.07.2002 US 209797

(43) Date of publication of application:
05.02.2003 Bulletin 2003/06

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Printed by Jouve, 75001 PARIS (FR)

Description

[0001] The present invention generally relates to devices for occluding a tissue opening such as a patent foramen ovale (PFO) or shunt in the heart, the vascular system, etc. and particularly provides an occluder device deliverable via a catheter to the site of a tissue opening.

[0002] The device of the subject invention, in all its embodiments, may be utilized for the occlusion of many types of tissue openings, such as septal defects and PFO, and the like. For the sake of clarity, the present invention may, at times, be described specifically in the context of occlusion of a PFO. This specific description, however, should not be taken to limit the scope of the possible applications of the present invention.

[0003] The term patent foramen ovale generally refers to the failure to close a normal opening between the left and right atria (i.e., upper chambers) of the heart. Typically, a foramen ovale is a flap-like opening between the left and right atria of the heart which persists long after birth. Commonly, the foramen ovale has one flap extending from the top of the atrial chamber and another flap extending from the bottom of the atrial chamber, wherein the two flaps meet or overlap each other. Specifically, a PFO is typically located between the atrial septum primum and secundum at the location of the fossa ovalis. The opening provides a path to allow blood to bypass the lungs in an unborn infant, since the lungs are not in use during that period. The foramen ovale typically becomes functionally closed after the birth of the infant due to greater pressure from the increased blood flow in the left atrium acting upon the flap. However, in humans, for example, as many as 1 in 5 people have foramen ovale that do not fully close. In the absence of other cardiac defects or unusual cardiac pressures, the open foramen ovale does not present a substantial problem. However, in patients having circulatory problems wherein the pressure on the right side of the heart is increased, for example as the result of congenital heart disease, blood may begin to flow through the foramen ovale. This result may also occur, for example, in divers when experiencing an increase in pressure due to being under water. The presence of a significantly large PFO, a flap structure that cannot provide sufficient seal, or a significant increase in pressure can cause blood to shunt across the defect from the right atrium to the left atrium and hence on to the left ventricle, aorta, and brain. If the defect is not closed, the risk of stroke is increased. Shunting of blood from the left to the right side can also have negative consequences, such as cardiac failure or hemoptysis.

[0004] Tissue openings have traditionally been corrected by open heart surgery which required the surgeon to open the chest of a patient and bypass the heart temporarily. The surgeon would then physically cut into the heart and suture the opening closed. In the case of larger defects, a patch of a biologically compatible material would be sewn onto the tissue to cover the opening. However, the risk of complications occurring during such an intricate procedure presents substantial problems that patients would rather avoid.

[0005] In order to avoid such complications and the long recovery times associated with open heart surgery, a variety of trans-catheter closure techniques have been implemented. In such techniques, an occluding device is delivered through a catheter to the site of the tissue opening. Once the occlusion device is positioned adjacent the opening, it must be attached to the tissue wall containing the opening in a manner that permits it to effectively block the passage of blood through the opening. Furthermore, the occlusion device must also adjust to the anatomy or structure of the PFO, commonly a tunnel like structure, the width and length of which varies substantially between patients. As has been documented in the literature, the trans-catheter techniques developed thus far have had drawbacks associated therewith. For example, a variety of heretofore known devices require assembly at the situs of the tissue opening. That is to say separable or separate halves of the device are deployed and subsequently united so as to traverse or span the tissue opening in furtherance of closure. Some well known devices require threading or buttoning of the discrete device elements. Additionally, such devices require special delivery and/or deployment tools, making their utility less than desirable.

[0006] A further shortcoming in the art yet to be adequately and fully addressed is the is-sue of device positioning at the situs and, more particularly, re-positioning in furtherance of fectuating a proper seal of the tissue opening. Also not addressed is the ability to re-trieve the device from the situs without damage thereto. Heretofore, known devices appear to evidence a broad functionality, namely that of occlusion, or more pointedly, plugging a tissue opening without a full or more developed functionality of the constituents or sub-structures of the device, e.g., a device which includes a single occluder reversibly secured in place by an anchor assembly.

[0007] Heretofore known self expanding devices tend to be structurally complex, expensive to produce and cumbersome to load, unload, and reliably position at the situs of a tissue opening, and insensitive to the variable requirements of the PFO tunnel geometry. The balance or tension between the structural integrity of the device, its size (e.g., bulk, rigidity, etc.), and ability to remain optimally positioned continues to be a critical consideration, cardiac devices being subject to the rhythmic pumping of the heart, on the order of 100,000 beats per day.

[0008] US 6,152,144 discloses a device and a method for obliterating or occluding a body cavity or passageway, in particular, the left atrial appendage of a patient's heart. The procedure can be carried out intraoperatively, but is preferably carried out percutaneously by use of a delivery catheter to position an occluding device adja-

cent a patient's left atrial appendage. The occluding device may prevent the passage of embolic or other material to or from the left atrial appendage by volumetrically filling the appendage, closing the opening of the appendage with an occluding member, or pulling the tissue around the opening of the appendage together and fixing it in a closed state.

[0009] WO 01/30367 discloses a membrane applied to the ostium of an atrial appendage is disclosed. The membrane prevents blood clots in the atrial appendage from escaping therefrom and entering the blood stream which can result in a blocked blood vessel, leading to strokes and heart attacks. The membrane is configured to extend over die ostium of the left atrial appendage. The membrane has an outer periphery with a dimension larger than a corresponding dimension of the ostium. Securement means is provided to secure the outer periphery of the membrane in direct engagement with the atrial wall surrounding die ostium. The securement means may be located between the membrane and the atrial wall, or the securement means may extend distally from the membrane through the ostium.

[0010] The EP 1 046 375 A1 shows an occlusion device according to the preamble of claims 1 and 15, for transcatheter operations. Such an occlusion device comprises a longitudinally elasticated fixing member having a shape-restoring force and being provided with a relatively large-sized, first and second circular portion at both ends thereof, and a closure membrane attached to the first circular portion and closing up an ring thereof. The first circular portion is fixed in a ring and connected to the second circular portion by means of a connecting portion extended form the fixed circular portion and progressively decreased in size toward the second circular portion. The second circular portion may be provided with a holding portion as occasion demands.

[0011] From the US-A-5 284 488 it is known to deliver a intravascular prostheses transarterially or transvenously to occlude cardiac defects. The defects which may include the patent ductus arteriosus, the ventricular septal defect and the atrial septal defect. The prostheses is a device having a distal occluder attached to a string and a proximal occluder connected to the string. The occluders are delivered to the heart by known methods. With the distal occluder on the distal side of the defect and the proximal occluder on the proximal side of the defect the occluders are adjusted according to the thickness of the heart structure at the defect.

[0012] In one embodiment the adjustment is by moving the distal occluder over a series of knot or buttons in the string. In another embodiment the proximal occluder is connected to the distal occluder by an elastic string so that the elastic tension of the strings bring the occluders into position. A radiopaque button is placed upon the string to aid positioning the occluders.

[0013] The present invention addresses the needs of the field, as well as other problems associated with the prior art. The present invention offers advantages over the prior art and solves problems associated therewith.

[0014] The present invention is a tissue opening occluder according to claim 1 and an apparatus according to claim 15. Advantageous embodiments of the invention are characterized in the sub-claims.

[0015] In an embodiment of the subject invention, one half of the occlusion device may be configured as an occluding panel (i.e., atrium engaging element), having two or three dimensions, while the second half may comprise a planar wire anchor structure which is configured to resiliently occupy a body structure, such as a PFO tunnel in furtherance of stabilizing the occluder panel portion of the device. The anchoring or positioning member may utilize one or more hook structures for engaging tissue surrounding the opening.

[0016] In yet a further embodiment of the subject invention, the device is adapted to be received and retained exclusively within the PFO tunnel, no structure thereof extending into the atrium. The anchor structure stabilizes an occluding panel such that the panel bridges the portions of the septum within the area of the defect.

[0017] In yet a further embodiment of the subject invention, the tissue opening occluder comprises eyelets wherein said eyelets are circular.

[0018] In yet a further embodiment of the subject invention, the tissue opening occluder comprises eyelets wherein said eyelets are elongate forms.

[0019] In yet a further embodiment of the subject invention, the tissue opening occluder comprises eyelets wherein said eyelets are angular forms.

[0020] The method of using the occluder comprises the steps of collapsing an occluder assembly in a deployment catheter; positioning the catheter proximate the tissue wall to deploy a first portion of the occluder assembly with a frame of the first portion in engagement with one side of the tissue wall; and maneuvering the catheter to deploy a wire frame anchor in engagement with an opposite side of the tissue wall, a discrete point on the first portion of the occluder assembly inter-linked, through the opening in the tissue wall, with a discrete point on the wire frame anchor.

[0021] Another method of using the occluder comprises the steps of collapsing an occluder assembly in a deployment catheter, the ocecluder assembly including an occluder portion, having a frame, adapted for interposition in the opening, and a generally linearly extending anchor carried by said occluder portion, said anchor having opposite ends extending beyond said perimeter to engage the tissue wall; positioning the catheter proximate the tissue wall; and deploying the occluder assembly into the opening, wherein the ends of the anchor extending beyond the perimeter to engage the tissue wall and fix said occluder assembly in the opening.

[0022] The present invention is thus an improved device over structures known in the prior art. More specific features and advantages obtained in view of those features will become apparent from the following specification with reference to the drawings in which:

FIG. 1 illustrates a side view of an anchored occluder of the subject invention sealing a PFO;
FIG. 1A is a plan view of the device of FIG. 1;
FIG. 2 illustrates the anchor structure of FIG. 1A;
FIG. 3 - 14 illustrate alternate embodiments of the device of FIG. 1, where FIG. 4 illustrates only the anchor portion of the device in combination with linkage structure;
FIG. 15 illustrates yet a further embodiment of the tissue opening occluder of the present invention, in side view, in a deployed condition; and,
FIGS. 16 - 17 illustrate embodiments of the occluder panel of FIG. 15.

[0023] As a preliminary matter, the subject invention contemplates three general configurations, several styles of each shown and subsequently described in the Figures. The general configuration for the tissue opening occluder (e.g., that structure illustrated in Figures 1 - 17) is characterized by a single occluder panel, functioning in a similar capacity as heretofore described, anchored by a substantially planar wire structure positionable for retention within the tunnel of the PFO (i.e., overlapping septal portions). A third con-figuration for the tissue opening occluder (e.g., those illustrated in Figures 24-26) is characterized by its deployed, occluding position, specifically its retention within a defect such that the device is effectively contained within a tunnel of a PFO so as to greatly reduce, if not eliminate, passage (i.e., shunting) of blood from the right to left atrium. Finally, a variety of advantageous linkages, namely those of Figures 3-9, facilitating operative engagement between the major structural elements of the several embodiments, are provided.

[0024] Referring to Figures 1 and 1A, a configuration of the tissue opening occlusion device 30 of the subject invention is illustrated in a fully deployed condition, fully engaged with portions of a tissue wall adjacent an opening or passage there-through, (e.g., foramen ovale) so as to effectively block blood flow through the passage. The reversibly deployable tissue opening occluder 30 generally includes first and second halves, more particularly, an occluder panel 32 and an anchor assembly 34 extending therefrom. The occluder panel 32 includes a fabric support structure 36 and fabric 38 (not shown in Figures 1 and 1A) supported by a perimeter thereof. Preferably, but not necessarily, the occluder panel 32 may embrace the panel styles previously noted. As will be later detailed, once the occluder panel 32 is reliably positioned relative to the septal wall, it may be anchored to, or at least relative to, the tissue wall via the anchor assembly 34, thereby eliminating the flow or shunting of blood through the opening or passageway.

[0025] The anchor assembly 34 of Figures 1 - 14 generally includes a wire anchor element 40 of generally planar configuration adapted to be selectively manipulatable in furtherance of positioning and securing the occluder panel 32 at a tissue opening situs. The wire anchor element 40, as shown, is intended to be positioned and retained within a characteristic tunnel of the PFO, as for instance by expansion of the structure into tensioned engagement with portions of the tunnel. The wire anchor element 40, as will be later discussed in detail, is at least indirectly linked to a central portion 42 of the fabric support structure 36, the occluder panel 32 and anchor assembly 34 being thereby opposingly urged into engagement with the tissue opening in furtherance of closure of the tissue opening or pas-sage. As will become evident, it is preferred that the wire anchor element 40 have a portion configured to snugly fit against a portion of the tissue wall, and that at least a portion of the wire anchor element 40 be wide enough to anchor or set the occluder panel 32 in place despite the forces being applied to the device generally by the fluid running through the structure (e.g., heart, vessel, etc.) in which the device is placed. It is to be further under-stood that the wire anchor element 40 may itself be a fabric support structure (i.e., function to suspend fabric from at least a perimeter thereof), to the extent that the addition or inclusion of fabric is advantageous in furtherance of seting, in a long term sense, the anchoring assembly (i.e., pseudo-assimilation of the structure to the tissue: further adherence of the structure to the tissue) post device deployment, or advantageous in immediate closure of the passage such as by clotting.

[0026] The anchor assembly 34 of the tissue opening occluder 30 further includes linkage 44 (not shown in Figures 1 and 1A) which joins the wire anchor element 40 to or with the occluder panel 32. This linkage 44 may be integral to the wire anchor element 40, as illustrated for instance in Figures 1 and 2, or may be a separate, discrete structure, see for instance FIG. 6, which is interposed between the wire anchor element 40 and the occluder panel 32. Generally, the functionality of the linkage is to permit a resilient multi-directional (i.e., in the Cartesian coordinate sense, namely the x, y, z directional senses) spacing of the device portions. It is advantageous that the wire anchor element 40 possess a high degree of freedom with respect to its motion relative to the occluder panel 32. In addition to the aforementioned x, y, and z motion, the ability to account for rotation (i.e., torsion) is desirable. It is preferable that the linkage be capable of reversible elongation. The occluder portions 32, 34 may be attached at a single point preferably at or near the center of the occluder panel 32, or, alternatively, conjoined at a plurality of discrete points, located or positioned within the bounds or adjacent the perimeter of each of the halves 32, 34 (i.e., within an area bounded by each perimeter of the physical structures 32, 34), or on the fabric 38 as applications warrant.

[0027] As an integral component of the wire anchor element 40, the linkage 44, more particularly the physical point of connection of the occluder panel 32 to the wire anchor element 40, is preferably an eyelet 46 (i.e., a loop). Similarly, the central portion 42 of the fabric support structure 36 of the occluder panel 32 preferably in-

cludes eyelet 46, or a plurality of eyelets, for engaging the linkage 44 of the anchor assembly 34. It is to be understood that as used herein, the term eyelet refers generally and broadly to a loop without limitation (e.g., round, elongate, angular, single, multiple (i.e., coil), etc.). In addition to convenient connection means, the eyelets impart a further resiliency or spring-like quality to the structures into which they are incorporated, thereby fortifying the cooperative action of the anchor assembly with the occluder panel.

[0028] As is appreciated with reference to the figures, the planar wire anchor element 40 preferably, but not necessarily, has a periphery that extends out into the atria when positioned in furtherance of device anchoring. More particularly, the wire anchor element 40 is oriented substantially parallel to the tissue wall. The anchor profile should be low so that tissue can grow into the implant and so that the implant does not cause flow disturbance or facilitate clot formation. It is preferred in these embodiments, that the angle of difference between the tissue wall and the wire anchor element be less than 45 degrees, but more preferably may be less than 15 degrees. This angle of difference is preferably measured from the central axis of the tissue wall.

[0029] Anchor shapes are provided which offer capability to conform to the geometry of a PFO tunnel and resistance to inadvertent ejection from the tunnel in the direction of the occluder panel. The PFO tunnel generally ranges from 3-10 mm in width and 1-20 mm in length and is generally flat in height with no thickness under at rest conditions. Anchors such as those shown in Figures 3, 5, 7, 8, 12 and 13 offer superior ability to conform to different or variable tunnel widths. Further, the generally planar geometry of anchors shown in Figures 3 - 14 conform to the generally planar geometry of the PFO tunnel. Further, anchors such as those shown in Figures 5, 6, 8, 10 and 12 offer superior resistance to ejection from the PFO tunnel once fully or partially deployed in the tunnel due to a portion of the anchor frame being substantially parallel to the occluder panel (as shown in the figures). Finally, designs such as the anchor in Figures 8 and 12 provide superior accommodation of variable PFO tunnel lengths while maintaining a frame edge that, when deployed, will resist ejection from the tunnel

[0030] It is further advantageous, however not necessary, that the anchor assembly 34, more particularly the wire anchor element 40, include one or more hooks 48 (e.g., Figures 7/7A) for attachment of the anchor assembly 34 to the tissue wall. In devices so equipped, the portion of the wire anchor element 40 having the hook or hooks 48 formed therein, or extending therefrom, will extend substantially parallel to the tissue wall. The one or more hooks may be formed, carried and/or arranged on or with respect to the wire anchor element 40 in any suitable manner known in the art. For example, as shown in Figures 7/7A, the wire anchor element 40 is formed having a hook 48 on an end opposite the attachment point of the two halves 32, 34. In this case, substantially the entire wire anchor element 40 will be generally aligned along the surface of the tissue wall (i.e., in conformity therewith) when the hook 48 thereof is engaged in the wall.

[0031] As previously noted, the occluder panel 32 comprises a fabric support structure 36 and fabric 38 supported or suspended by a perimeter thereof. The fabric support structure 36 of the occluder panel 32 is generally flexible and elastically deformable. Fabric 38, which may be formed of a thin, flexible material which can be folded and pulled taut without being damaged, is suspended or otherwise affixed to the perimeter of the fabric support structures 36. It may be desirable to provide an excess of fabric to the panel 32 or the anchor 40 so as to facilitate collapse of the fabric carrying structure into a catheter.

[0032] The fabric 38 is preferably a relatively porous material. While this may seem to contradict the purpose of the device, blood will tend to coagulate on the latticework provided by the porous material. Blood flow across the tissue opening is usually substantially blocked after minimal time passage. If so desired, the fabric 38 of the occluder panel 32 may be treated with a thrombogenic agent to speed this natural process, or may be impregnated with a biocompatible polymeric compound or the like to make it relatively impervious to fluids.

[0033] The primary purpose of using a porous fabric is to accelerate the process of permanently anchoring the device in place. The support structures hold the fabric tautly and in intimate contact with the surface of the tissue wall. This intimate contact between the tissue wall and perimeter of the occluder permits ingrowth of collagen and fibrous tissue from the tissue wall into the fabric. Over time, the membrane resting against the tissue wall will become securely anchored to the wall and be covered by a layer of endothelial cells. Elastic polymeric materials such as, for example, polyester knit, nylon, polypropylene, polytetrafluoroethylene (e.g., Teflon® 7), and expanded polytetrafluoroethylene (e.g., Gore-Tex® 7), as well as natural fabrics such as silk, are suitable materials for covering the fabric support structure 36 of the occluder panel 32.

[0034] To accommodate the need of the fabric support structure 36 to distort when retrieving the device 30 into a catheter, excess fabric can be provided. On an area basis relative to the support structure, an excess of fabric in the range, typically, of about 30-35 percent, and up to 50 percent, is sufficient. This range is required because the low stretch characteristics of the fabric prevent the support structure from collapsing in a manner suitable to get into the catheter. However, a 30 denier polyester knit is advantageous in that it possesses a low stretch character, is approximately 50% less bulky than known jersey style knit patterns which facilitates the use of smaller delivery catheters, and allows for the de-vice of the subject invention to be retrieved into such catheters at forces that are not detrimental to either the catheter or the device (e.g., a 40 mm occluder may be pulled

into a 12 French catheter using a reasonable peak force of about four pounds).

[0035] The fabric 38 may be attached to support structures 36, or wire anchor element 40 as the case may be, by any suitable means. For instance, the fabric 38 may be directly attached to the support structures 36 by means of an adhesive or the like, or the periphery of the fabric 38 may be wrapped about the support structures 36 and the peripheral edge attached to the rest of the fabric so as to essentially define a sleeve about the support structures 36. In the latter instance, the sleeve may fit the support structure relatively loosely so that the structure may move within the sleeve with respect to the fabric. The peripheral edge of the fabric may be affixed to the rest of the fabric sheet 38 in any suitable fashion such as by sewing. Preferably, though, the periphery of the fabric can be sewn to at least some portion of the perimeter segments of the support structures 36 using a polyester, non-adsorbable suture or the like.

[0036] The planar wire anchor element 40 and the fabric support structure 36 are preferably formed of a flexible, elastically deformable material such as a biocompatible metal, metal alloy or polymer, most preferably a superelastic material. One such material currently known in the art is a near-stoichiometric nickel/titanium alloy, commonly referred to as Nitinol or NiTi. Such superelastic materials may be elastically deformed to a much greater extent than most other materials, yet substantially fully recover their original shape when released. This permits the frame to be deformed sufficiently for insertion into, and passage through, a small-diameter catheter, yet automatically elastically return to its initial shape upon exiting the catheter.

[0037] The frame portions are preferably manufactured with nitinol wire that can be wound around the pins of a forming die and subjected to heat treatment. The wire may be bent through greater than 360 degrees to form the loops or eyelets. The ends of the wire may be attached to each other in any secure fashion, such as by means of welding, a suitable biocompatible cementitious material, or by any means known in the art. For example, the wire ends of each frame half can be connected with a titanium hypo tube using a compression crimp. Titanium is more ductile than nitinol, providing a reliable grip with excellent corrosion resistance, thereby making this method suitable for joining the ends of the material. Alternately, the preferred forms for the fabric support and/or the wire anchor element may be cut out from a sheet of such superelastic material as a single structure, by chemical etching, punching with a suitable punch and die, or any other appropriate forming method.

[0038] In order to enhance radiopacity so that the device can be viewed remotely during deployment, either the fabric support structure 36 or the wire anchor element (or both) may be provided with a radiopaque coating, such as gold or platinum. For instance, the wire may be plated with a thin layer of gold or platinum. For instance, a helically wound length of a thin radiopaque wire may be placed over the wire, alternatively, radiopaque marking bands, which are commercially available, may be employed. By placing one such band on segments of device structures, a physician can remotely visualize the frame as a plurality of small bands; when the bands are appropriately spaced from one another on a monitor, the physician knows that the frame is properly deployed. Alternatively, the fabric support structures can be made of wire with a radiopaque core.

[0039] With general reference to Figures 3 - 14, alternate embodiments of the tissue opening occluder 30 of the subject invention are illustrated, more particularly numerous configurations for the anchor assemblies 34 (e.g., the planar wire anchor elements 40): an eye (Figures 3 and 4); mushroom heads (Figures 5, 6, 7, and 9); lobed elements (Figures 10 - 12); and the styles which are the subject of Figures 8, 13 and 14. The embodiments of Figures 6 - 9 show a discrete linkage 44 interposed between the occluder panel 32 and the anchor assembly 34 so as to define a non-stressed spaced apart condition for said structures.

[0040] Figures 15 - 17 illustrate a further embodiment of the tissue opening occluder of the present invention in a deployed configuration. Figures 16 and 17 illustrate the construction of the occluder panel 32. The panel 32 includes a fabric support structure 36 which is shown as having a plurality of eyelets 46 formed therein. A fabric swatch 38 is mounted to the fabric support structure 36 in an appropriate manner such as by means of suturing (not shown).

[0041] Figures 16 and 17 illustrate an anchor element 40. As discussed generally herein with regard to all embodiments, upon the occluder panel 32 being deployed into position within the PFO infudibulum, the anchor element 40 can be allowed to spring into an expanded configuration in which it operatively functions to hold the occluder panel 32 in position within the infudibulum.

[0042] The anchor element 40 of Figures 15 - 17 is a generally straight wire segment which, when to be deployed from, for example, a catheter (not shown), springs to its operational configuration at least in secure engagement with heart tissue. In some instances, however, the anchor element 40 would spring into, and pass through, the heart tissue. That is the disposition illustrated in Figure 15.

[0043] It will be understood that the fabric support structure can, in some embodiments, comprise a single continuous wire made of nitinol. A structure employing multiple nitinol sections, however, can also be utilized. The swatch of fabric is made of any appropriate material discussed hereinbefore. In any case, the material of which it is made will function to promote tissue growth within the PFO infudibulum.

[0044] It will be understood that insertion of the occluder panel 32 into the PFO infudibulum will be accomplished in a manner known in the prior art. Typically, a nitinol fabric support structure would be positioned within a deployment catheter in a contracted configuration.

ter the catheter has been inserted through a patients vasculature to arrive at the PFO, it can be deployed in an appropriate manner known in the prior art. Appropriate deployment techniques are taught in US-A-6,214,029.

[0045] Although the foregoing has focused on application of the present invention to occlude atrial PFO, the invention is not limited to occluding only foramen ovale. For instance, the instant occlusion device can be used to treat atrial septal defect, ventricular septal defect, patent ductus arteriosus, or any other congenital or acquired orificial or tubular communications between vascular chambers or vessels. While a preferred embodiment of the present invention has been described, it should be understood that various changes, adaptations and modifications may be made therein without departing from the scope of the claims.

Claims

1. A reversibly deployable tissue opening occluder comprising

   - an occluder panel (32) and an anchor assembly (34) extending therefrom,
   - said occluder panel (32) comprising a fabric support structure (36) and fabric supported by a perimeter thereof,
   - said anchor assembly (34) comprising a planar wire anchor element (40),

   characterised in that

   - said wire anchor element (40) is at least indirectly linked to a central portion of said fabric support structure (36) by a linkage such that
   - said occluder panel (32) and said anchor assembly (34) are thereby opposingly urged into engagement with the tissue opening in furtherance of closure, and

   said anchor assembly (34) is adapted to be selectively manipulatable in furtherance of positioning and securing said occluder panel (32) at a tissue opening situs, wherein the generally planar geometry of said anchor assembly (34) conforms to the generally planar geometry of a tissue opening, wherein said anchor assembly (34) is configured for placement within a tunnel of the tissue opening, for engagement with portions of the tissue wall within this tunnel and for substantially parallel orientation to the tissue wall.

2. The occluder of claim 1 or 3, wherein said linkage (44) is capable of reversible elongation.

3. The occluder of claim 1 or 3, wherein said linkage (44) comprises a suture.

4. The occluder of claim 1 or 3, wherein said linkage (44) comprises a wire or a wire segment or a wire structure.

5. The occluder of claim 1 or 3, wherein said linkage (44) comprises at least a single loop.

6. The occluder of claim 1 or 3, wherein said linkage (44) comprises at least a single spring element.

7. The occluder of claim 2, wherein said fabric support structure (36) includes at least a single eyelet (46).

8. The occluder of claim 9, wherein said at least one single eyelet (46) comprises at least a single coil formed integral to said fabric support structure (36).

9. The occluder of claim 10, wherein said at least one single eyelet (46) is located within said central portion of said fabric support structure (36).

10. The occluder of claim 11, wherein said anchor assembly (34) extends from said at least one single eyelet (46).

11. The occluder of claim 12, wherein said planar wire anchor element (40) includes at least a single eyelet (46).

12. The occluder of claim 13, wherein said planar wire anchor element eyelet (46) is connected to the fabric support structure eyelet (46).

13. The occluder of claim 14, wherein said wire anchor element (40) includes at least a single tissue engaging hook.

14. The occluder of any of the preceding claims, wherein an angle of difference between a tissue wall and the wire anchor element (40) is less than 45 degrees, measured from the central axis of the tissue wall.

15. A reversibly deployable tissue opening occluder comprising

   - an occluder panel (32) adapted for interposition in the opening, said occluder panel (32) including a frame defining a perimeter;
   - a generally linearly extending anchor (34) carried by said occluder panel (32), said anchor (34) having opposite ends extending beyond said perimeter to engage the tissue wall and fix said occluder panel (32) in the tissue opening;

   characterised in that

   a generally planar geometry of said anchor assembly (34) conforms to the generally planar geometry

of a tissue opening, wherein said anchor assembly (34) is a generally straight wire segment which, when being deployed, springs to its operational configuration at least in secure engagement with the wall of the tissue opening.

16. The apparatus of claim 17, wherein said anchor assembly (34) is integral with said frame.

17. The apparatus of claim 17, wherein said anchor assembly (34) and said frame are formed of nitinol or of a knitpolyester

18. The apparatus of any of claims 17 to 19, wherein said occluder panel (32) is oriented substantially parallel to the tissue wall.

Patentansprüche

1. Ein reversibel ausfahrbarer Okklusionsverschluß für Gewebeöffnungen umfassend

   - eine Verschlußplatte (32) und eine sich von dieser erstreckende Verankerungsanordnung (34),
   - wobei die Verschlußplatte (32) eine Gewebestützstruktur (36) und von ihrem Umfang unterstütztes Gewebe umfasst,
   - wobei die Verankerungsanordnung (34) ein ebenes Drahtverankerungselement (40) umfasst,

   dadurch gekennzeichnet, dass

   - das Drahtverankerungselement (40) wenigstens indirekt derartig über eine Verbindung mit einem zentralen Abschnitt der Gewebestützstruktur (36) verbunden ist,
   - dass die Verschlußscheibe (32) und die Verankerungsanordnung (34) **dadurch** entgegengesetzt in Eingriff mit der Gewebeöffnung gedrückt werden, um diese zu schließen, und
   - die Verankerungsanordnung (34) derart ausgestaltet ist, dass sie gezielt manipulierbar ist, um die Verschlußscheibe (32) an der Stelle von Gewebeöffnungen zu positionieren und zu befestigen, wobei die im wesentlichen planare Geometrie der Verankerungseinrichtung (34) der im wesentlichen planaren Geometrie einer Gewebeöffnung entspricht, wobei die Verankerungseinrichtung (34) konfiguriert ist, um in einem Tunnel der Gewebeöffnung plaziert zu werden, um mit Teilen der Gewebewand innerhalb des Tunnels verbunden zu werden und im wesentlichen parallel zu der Gewebewand angeordnet zu werden.

2. Okklusionsverschluß gemäß Anspruch 1, worin die Verbindung (44) in Längsrichtung gedehnt werden kann.

3. Okklusionsverschluß gemäß Anspruch 1, worin die Verbindung (44) eine chirurgische Naht umfasst.

4. Okklusionsverschluß gemäß Anspruch 1, worin die Verbindung (44) einen Draht oder ein Drahtsegment oder eine Drahtstruktur umfasst.

5. Okklusionsverschluß gemäß Anspruch 1, worin die Verbindung (44) wenigstens eine einzelne Schlaufe umfasst.

6. Okklusionsverschluß gemäß Anspruch 1, worin die Verbindung (44) wenigstens ein einzelnes Federelement umfasst.

7. Okklusionsverschluß nach Anspruch 1, worin die Gewebeunterstützungsstruktur (36) wenigstens eine einzelne Öse (46) umfasst.

8. Okklusionsverschluß gemäß Anspruch 7, worin die wenigstens eine Öse (46) wenigstens eine Wicklung umfasst, die einstückig mit der Gewebeunterstützungsstruktur (36) ausgebildet ist.

9. Okklusionsverschluß gemäß Anspruch 8, wobei die wenigstens eine Öse (46) im zentralen Abschnitt der Gewebeunterstützungsstruktur (36) angeordnet ist.

10. Okklusionsverschluß gemäß Anspruch 9, worin die Verankerungsanordnung (34) sich von der wenigstens einen Öse (46) aus erstreckt.

11. Okklusionsverschluß gemäß Anspruch 10, worin das ebene Drahtverankerungselement (40) wenigstens eine einzelne Öse (46) enthält.

12. Okklusionsverschluß gemäß Anspruch 11, worin die Öse (46) in jenem ebenen Drahtverankerungselement mit der Öse (46) in der Gewebeunterstützungsstruktur verbunden ist.

13. Okklusionsverschluß gemäß Anspruch 12, worin das drahtförmige Verankerungselement (40) wenigstens einen einzelnen Gewebeverbindungshaken enthält.

14. Okklusionsverschluß nach einem der vorhergehenden Ansprüche, worin der Differenzwinkel zwischen einer Gewebewand und dem Drahtverankerungselement (40), gemessen von der Zentralachse der Gewebewand, weniger als 45° beträgt.

15. Ein reversibel ausfahrbarer Okklusionsverschluß

für Gewebeöffnungen umfassend:

- eine Verschlußplatte (32), die angepasst ist, um in die Öffnung eingeführt zu werden, wobei die Verschlußplatte (32) einen Rahmen enthält, der einen Umfang definiert;
- ein im wesentlichen linear ausgestreckter Anker (34), der von der Verschlußscheibe (32) getragen wird, wobei der Anker (34) gegenüberliegende Enden hat, die sich über den Umfang hinaus erstrekken, um in die Gewebewand einzugreifen und die Verschlußscheibe (32) in der Gewebeöffnung zu befestigen;

dadurch gekennzeichnet, dass

- eine im wesentlichen ebene Geometrie der Verankerungsanordnung (34) der im wesentlichen ebenen Geometrie einer Gewebeöffnung entspricht, wobei die Verankerungseinrichtung (34) ein im wesentlichen gerades Drahtelement ist, das, wenn es ausgefahren ist, in seinen Betriebszustand springt, in dem es wenigstens in sicherer Verbindung mit der Wand der Gewebeöffnung ist.

16. Vorrichtung gemäß Anspruch 15, worin die Verankerungsvorrichtung (34) in den Rahmen eingebaut ist.

17. Vorrichtung gemäß Anspruch 15, worin die Verankerungsvorrichtung (34) und der Rahmen aus Nitinol oder Maschenpolyester geformt sind.

18. Vorrichtung nach einem der Ansprüche 15 bis 17, worin die Verschlußplatte (32) im wesentlichen parallel zu der Gewebewand angeordnet ist.

Revendications

1. Dispositif d'occlusion qui peut être déployé de manière réversible comprenant:

- un panneau d'occlusion (32) et un ensemble d'ancrage (34) s'étendant de là,
- ledit panneau d'occlusion (32) comprenant une structure de support de matériel (36) et le matériel supporté par un périmètre de celui,
- ledit ensemble d'ancrage (34) comprenant un élément d'ancrage de fil plat (40)

caractérisé par

- ledit élément d'ancrage de fil (40) est au moins indirectement lié à une portion centrale de ladite structure de support de matériel (36) par une liaison que
- ledit panneau d'occlusion (32) et ledit ensemble d'encrage (34) sont de cette manière poussés en sens contraire en engagement avec l'ouverture du tissu dans l'avancement de la fermeture, et
- ledit ensemble d'encrage (34) est adapté pour être manipulé sélectivement dans l'avancement de positionnement et en assurant ledit panneau d'occlusion (32) à un situs de l'ouverture de tissu, où la géométrie généralement planaire dudit ensemble d'ancrage (34) est conforme à la géométrie généralement planaire d'ouverture de tissu, où ledit ensemble d'encrage (34) est configuré pour placement à l'intérieur d'un tunnel de l'ouverture du tissu pour engagement avec les portions de la paroi du tissu à l'intérieur de ce tunnel et pour orientation substantiellement parallèle à la paroi du tissu.

2. Dispositif d'occlusion selon la revendication 1 ou 3, où ladite liaison (44) est capable d'élongation réversible.

3. Dispositif d'occlusion selon la revendication 1 ou 3, où ladite liaison (44) comprend une suture.

4. Dispositif d'occlusion selon la revendication 1 ou 3, où ladite liaison (44) comprend un fil ou un segment de fil ou une structure de fils.

5. Dispositif d'occlusion selon la revendication 1 ou 3, où ladite liaison (44) comprend au moins une seule boucle.

6. Dispositif d'occlusion selon la revendication 1 ou 3, où ladite liaison (44) comprend au moins un seul élément de ressort.

7. Dispositif d'occlusion selon la revendication 2, où ladite structure de support de matériel (36) comprend au moins une seule oreille (46).

8. Dispositif d'occlusion selon la revendication 7, où ladite au moins une seule oreille (46) comprend au moins une seule spire formée intégralement à ladite structure de support de matériel (36).

9. Dispositif d'occlusion selon la revendication 8, où ladite au moins une seule oreille (46) est logée à l'intérieur de ladite portion centrale de ladite structure de support de matériel (36).

10. Dispositif d'occlusion selon la revendication 9, où ledit ensemble d'ancrage (34) s'étend à partir de ladite au moins une seule oreille (46).

11. Dispositif d'occlusion selon la revendication 10, où ledit élément d'encrage de fils plats (40) comprend

au moins une seule oreille (46).

12. Dispositif d'occlusion selon la revendication 11, où ladite oreille de l'élément d'ancrage de fil plat (46) est connectée à l'oreille de la structure de support de matériel (46).

13. Dispositif d'occlusion selon la revendication 12, où ledit élément d'ancrage de fil (40) comprend au moins un seul crochet d'engagement du tissu.

14. Dispositif d'occlusion selon l'une quelconque des revendications antérieures, où un angle de la différence entre une paroi du tissu et l'élément d'ancrage de fil (40) est plus petit que 45 degrés, mesuré à partir de l'axe central de la paroi du tissu.

15. Dispositif d'occlusion qui peut être déployé de manière réversible comprenant:

- un panneau d'occlusion (32) adapté pour interposition dans l'ouverture, ledit panneau d'occlusion (32) incluant un cadre définissant un périmètre;
- une ancre s'étendant généralement de manière linéaire (34) portée par ledit panneau d'occlusion (32), ladite ancre (34) ayant les extrémités opposées s'étendant au-delà dudit périmètre pour engager la paroi du tissu et fixer ledit panneau d'occlusion (32) dans l'ouverture du tissu;

caractérisé par une géométrie généralement planaire dudit ensemble d'ancrage (34) qui est conforme à la géométrie généralement planaire de l'ouverture du tissu, où ledit ensemble d'ancrage (34) est un segment de fil généralement plat qui, quand étant déployé, saute à sa configuration opérationnelle au moins en engagement sûr avec la paroi de l'ouverture du tissu.

16. Appareil selon la revendication 15, où ledit ensemble d'ancrage (34) est intégral avec ledit cadre.

17. Appareil selon la revendication 15, où ledit ensemble d'ancrage (34) et ledit cadre sont formés de nitinol ou d'un knitpolyester.

18. Dispositif d'occlusion selon l'une quelconque des revendications 15 à 17, où ledit panneau d'occlusion (32) est orienté substantiellement parallèle à la paroi du tissu.

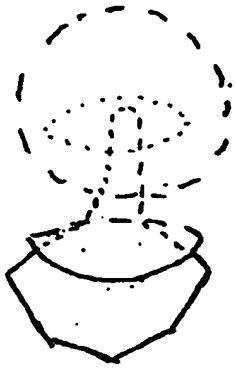

Fig: 1A

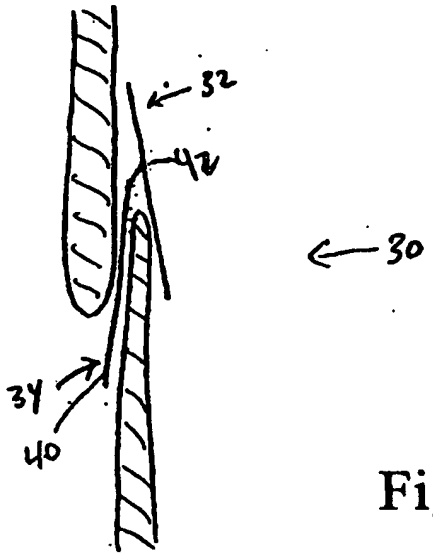

Fig: 1

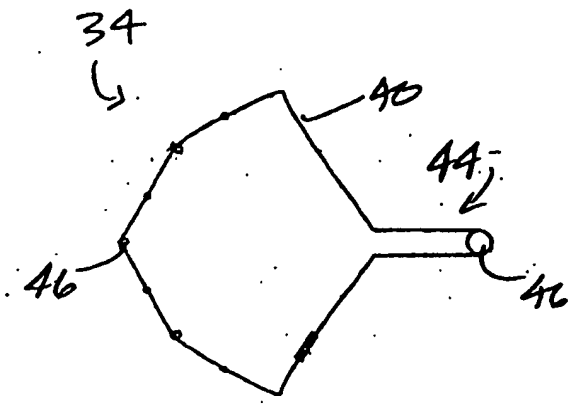

Fig: 2

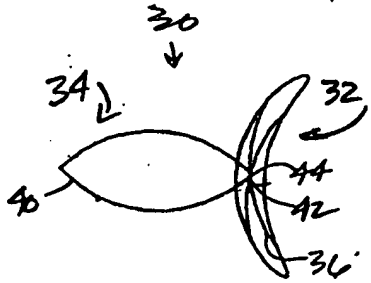

Fig: 3

Fig: 4

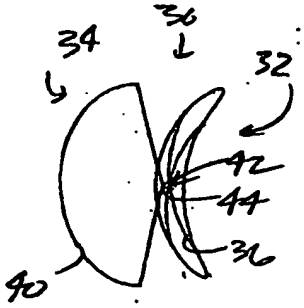

Fig: 5.

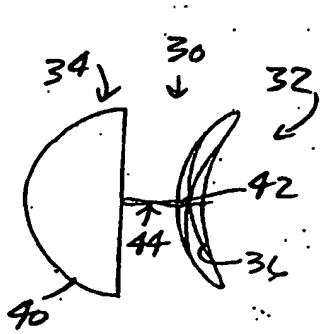

Fig: 6

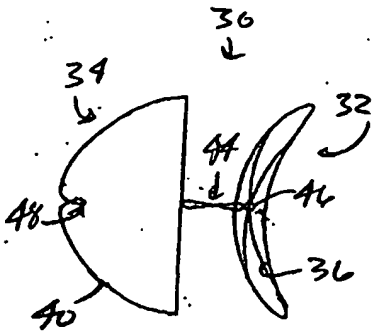

Fig: 7

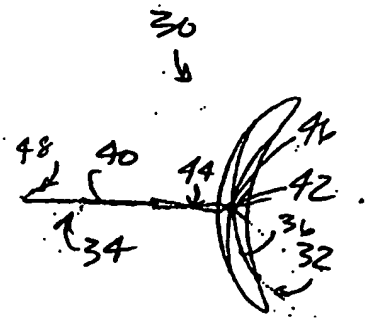

Fig: 7A

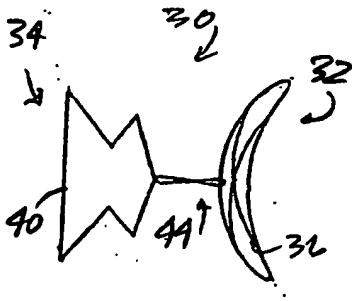

Fig: 8

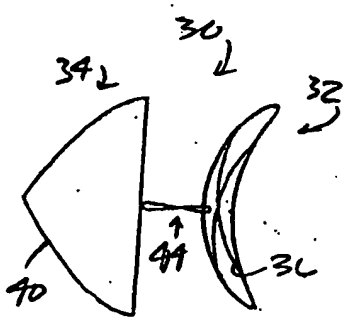

Fig: 9

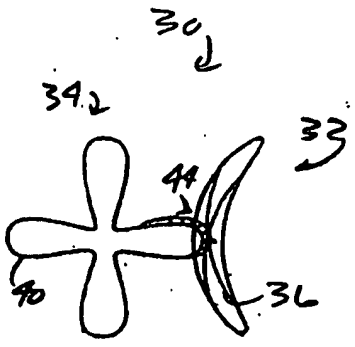

Fig: 10

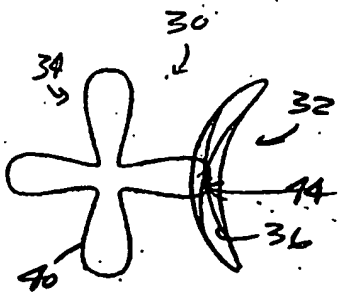

Fig: 11

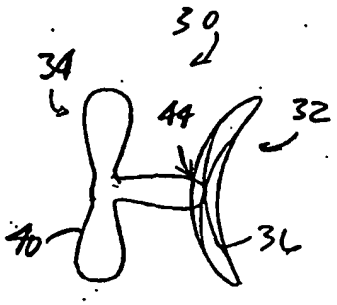

Fig: 12

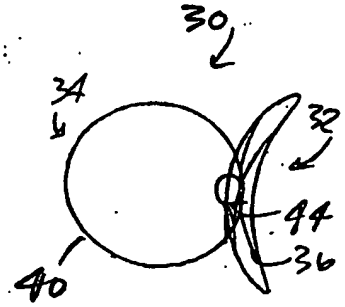

Fig: 13

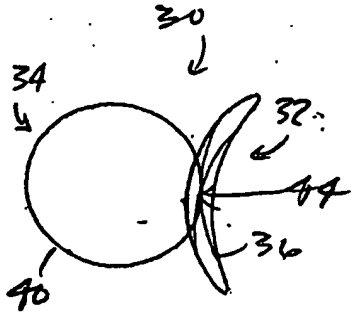

Fig: 14

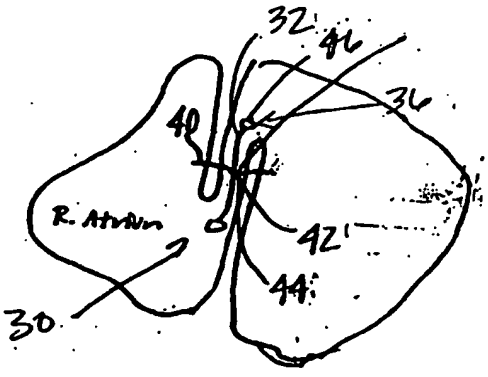

Fig: 15

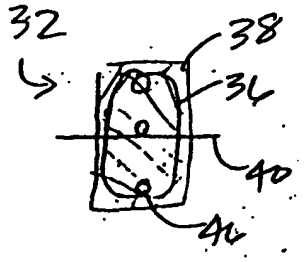

Fig: 16

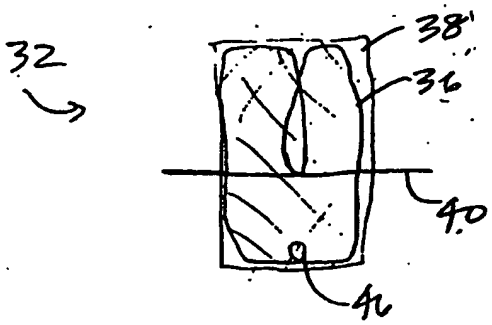

Fig: 17